

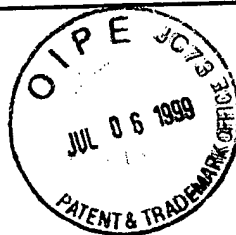
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UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
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09/26/97 02/24/99 FILING



M 48194

0232/0324  
DIPE, BRONSTEIN, ROBERTS & CUSHMAN  
130 WATER STREET  
BOSTON, MA 02109

NOT ASSIGNED

1614  
DATE MAILED:

03/24/99

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS  
CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application fails to comply with the requirements of 37 CFR 1.821 - 1.825.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked-up copy of the "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).
- ☐ 7. OTHER: \_\_\_\_\_

**APPLICANT MUST PROVIDE:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing."
- ☒ An initial or substitute paper copy of the "Sequence Listing," as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

**FOR QUESTIONS REGARDING COMPLIANCE WITH THESE REQUIREMENTS, PLEASE CONTACT:**

- ☐ For Rules Interpretation, call (703) 308-1123.
- ☐ For CRF submission help, call (703) 308-4212.
- ☐ For PatentIn software help, call (703) 308-6856.

*D. Rates*  
Customer Service Center  
Initial Patent Examination Division (703) 308-1202

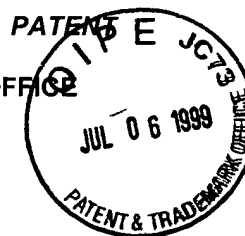
THIS COPY TO BE RETURNED WITH RESPONSE

Practitioner's Docket No. 48194(342)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: F. Masahiko

Serial No.: 09/257,650      Group No.: 1614  
Filed: February 25, 1999      Examiner: Not Assigned  
For: USE AND SCREENING METHOD FOR AN ABERANT GENE PRODUCT  
OPERATING SUBSTANCE



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JUL 13 1999

Box Sequence  
Assistant Commissioner for Patents  
Washington, D.C. 20231

TECH CENTER 1600/2900

SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY, AND/OR  
AMENDMENT PERTAINING THERETO FOR BIOTECHNOLOGY INVENTION  
CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE

*(check and complete this item, if applicable)*1. ☒ This replies to the Notice To Comply dated March 24, 1999☒ A copy of the Office Letter is enclosed.

---

**CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10\***

(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**☒ deposited with the United States Postal Service in an envelope addressed to the Assistant commissioner for Patents, Washington, D.C. 20231

37 CFR 1.8 (a)

37 CFR 1.10\*

☒ with sufficient postage as first class mail.    ☐ as "Express Mail Post Office to Addressee"

Mailing Label No. \_\_\_\_\_ (mandatory)

**TRANSMISSION**☐ transmitted by facsimile to the Patent and Trademark Office.

Date:

July 2, 1999

Signature

Maureen T. Whalen

(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by Express Mail must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C. F. R. 1.10(b). "Since the filing of correspondence under §1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition. "Notice of Oct.24, 1996, 60 Fed. Reg. 56,439, at 56,442.

## IDENTIFICATION OF DECLARANT

2. I, Cara Z. Lowen  
(type or print name of declarant signing below)

state the following:

### ITEMS BEING SUBMITTED

3. Submitted herewith is/are

*(check each item as applicable)*

- A. ☒ "Sequence Listing(s)" for the nucleotide and/or amino acid sequence(s) in this application. Each "Sequence Listing" is assigned a separate identifier as required in 37 C.F.R. § 1.821(c) and 37 C.F.R. §§ 1.822 and 1.823.
- B. ☒ An amendment to the description and/or claims, wherein reference is made to the sequence by use of the assigned identifier, as required in 37 C.F.R. § 1.821(d).
- C. ☒ A copy of each "Sequence Listing" submitted for this application in computer readable form, in accordance with the requirements of 37 C.F.R. §§ 1.821(e) and 1.824.
- D. ☐ Please transfer to this application, in accordance with 37 C.F.R. § 1.821(e), the computer readable copy(ies) from applicant's other application identified as follows:

In re application of:

Serial No.: /

Group No.:

Filed:

Examiner:

For:

The Computer readable form(s) of applicant's other application corresponds to the "Sequence Identifier(s)" of the application as follows:

Computer Readable Form

"Sequence Identifier"

(other application)

(this application)

(Submission--Nucleotide and/or Amino Acid Sequence [9-37]--page 2 of 6)

NOTE: "If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference maybe made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application. The new application shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified" 37 C.F.R. 1.821(e)

- E. ☒ A statement that the content of each "Sequence Listing" submitted and each computer readable copy are the same, as required in 37 C.F.R. § 1.821(g).
- ☒ Because the statement is not made by a person registered to practice before the Office, the Statement is verified as required in 37 C.F.R. § 1.821(b).
- F. ☒ Because this submission is made in fulfilling the requirement under 37C.F.R. § 1.821(g), a statement that the submission includes no new matter.
- ☒ Because the statement is not made by a person registered to practice before the Office, the statement is verified, as required in 37 C.F.R. § 1.821(g).

**STATEMENT THAT "SEQUENCE LISTING" AND COMPUTER READABLE COPY ARE THE SAME AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER**

4. I hereby state:  
*(complete applicable item A and/or B)*
- A. ☐ Each computer readable form submitted in this application, including those forms requested to be transferred from applicant's other application, is the same as the "Sequence Listing" to which it is indicated to relate.
- B. ☐ All papers accompanying this submission, or for which a request for transfer from applicants' other application, introduce no new matter.

**VERIFICATION**

5. NOTE: "Such a statement must be verified statement if made by a person not registered to practice before the Office." 37 C.F.R. § 1.821(f) and (g).
- ☐ I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**STATUS**

6. Applicant is
- ☐ a small entity. A verified statement:  
    ☐ is attached.  
    ☐ was already filed.  
    ☐ will follow.
- ☒ other than a small entity.

## EXTENSION OF TERM

7.

**NOTE:** "Extension of Time in Patent Cases (Supplement Amendments)-If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.

If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run. Notice of Dec.10, 1985 (1061 O.G. 34-35).

**NOTE:** See 37 C.F.R. 1.645 for extensions of time in interference proceedings and 37 C.F.R. 1.550(c) for extensions of time in reexamination proceedings.

8. The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136 apply.

(complete (a) or (b) as applicable)

- (a) ☐ Applicant petitions for an extension of time under 37 C.F.R. 1.136 (fees: 37 C.F.R. 1.17(a)-(d)) for the total number of months checked below:

Extension (months)	Fee for other than small entity	Fee for small entity
<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 380.00	\$ 190.00
<input type="checkbox"/> three months	\$ 870.00	\$ 435.00
<input type="checkbox"/> four months	\$ 1,360.00	\$ 680.00

Fee \$ \_\_\_\_\_

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for \_\_\_\_\_ months has already been secured. The fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ \_\_\_\_\_

OR

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

## FEE PAYMENT

9. ☐ Attached is a check in the sum of \_\_\_\_\_  
☐ Charge Account No. \_\_\_\_\_ the sum of \$ \_\_\_\_\_  
A duplicate of this transmittal is attached.

(Submission--Nucleotide and/or Amino Acid Sequence [9-37]--page 4 of 6)

FEE DEFICIENCY

10.

NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO Finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.

11. ☒ If any additional extension and/or fee is required, charge  
Account No. 04-1105

SIGNATURE(s)

Cara Z. Lowen

(type or print name of person signing declaration)

Cara Z. Lowen 7/2/99  
Signature

Dike, Bronstein, Roberts & Cushman, LLP  
130 Water Street  
Boston, MA 02109  
Telephone No. (617) 523-3400

- ☐ Inventor(s)  
☐ Assignee of complete interest  
☐ Person authorized to sign on behalf of assignee  
☐ Practitioner of record  
☒ Filed under Rule 34(a)  
☒ Registration No. 38,227  
☐ Other \_\_\_\_\_  
(specify identity of declarant)

(complete the following, if applicable)

\_\_\_\_\_  
(type name of assignee)

\_\_\_\_\_  
Address of assignee

\_\_\_\_\_  
Title of person authorized to sign on behalf of assignee

A "CERTIFICATE UNDER 37 C.F.R. 3.73(b)" is attached.

Assignment recorded PTO on \_\_\_\_\_

Reel \_\_\_\_\_ Frame \_\_\_\_\_

Reg. No.: 38,227

Tel. No.: (617) 523-3400

Cara Z. Lowen 7/2/99  
SIGNATURE OF PRACTITIONER

Cara Z. Lowen

(type or print name of practitioner)

DIKE, BRONSTEIN, ROBERTS &  
CUSHMAN, LLP

130 Water Street

Boston, MA 02109-4280

(Submission--Nucleotide and/or Amino Acid Sequence [9-37]--page 6 of 6)

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GP 1614 W/D  
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Application of: F. Masahiko Examiner: Not Assigned  
Serial No: 09/257,650 Group No.: 1614  
Filed: February 25, 1999  
For: USE AND SCREENING METHOD FOR AN ABERANT GENE  
PRODUCT-OPERATING SUBSTANCE

JUL 12 1999

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Washington, D.C. 20231

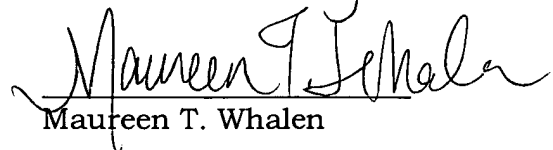
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**CERTIFICATE OF MAILING**

I hereby certify that this SUBMISSION OF "SEQUENCE LISTING", COMPUTER READABLE COPY, AND/OR AMENDMENT PERTAINING THERETO FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE (Transmittal), COPY OF COMMUNICATION DATED MARCH 24, 1999, STATEMENT IN SUPPORT OF FILING AND SUBMISSION IN ACCORDANCE WITH 37 CFR §§1.821-1.825, SEQUENCE LISTING COMPUTER PRINTOUT, 3.5" FLOPPY DISK CONTAINING THE SEQUENCE LISTING, AMENDMENT, ADDED PAGE (Sheet 1) for the above-identified Application are being deposited with the United States Postal Service as first class mail in an envelope addressed to BOX SEQUENCE, Assistant Commissioner For Patents, Washington, D.C. 20231 on this 2<sup>nd</sup> day of July, 1999.

  
Maureen T. Whalen

125862